December 20, 2005

Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 2002N-0273

Dear Sir or Madam:

On behalf of the consumer organization Food and Water Watch, we welcome this opportunity to comment on the proposed rule, "Substances Prohibited From Use in Animal Food or Feed."

We would like to express our disappointment in the proposed rule as presently written. It is a radical departure from the proposed actions that officials from both the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) articulated on this issue in a press conference on January 26, 2004, when they said they would eliminate the possible contamination of animal feed with bovine spongiform encephalopathy (BSE). The proposed rule is a retreat from those measures announced in 2004. As your commentary admits, this new rule will only remove ninety percent of any remaining potential infectivity from possible spread through the feed system (70 FR 58587). The ruminant population and American consumers deserve to have a feed ban in place that removes one hundred percent of the risk from BSE from entering the food supply, and that is why we do not believe the current rule goes far enough.

On January 26, 2004, then-HHS Secretary Tommy Thompson and then-FDA Commissioner Mark McClellan announced that the following measures were going to be part of an interim final rule on animal feed:

- The prohibition of feeding ruminants mammalian blood and blood products as a protein source since there has been evidence that blood can carry BSE;

- A ban on the use of poultry litter as a feed ingredient for ruminant animals. Poultry litter consists of bedding, spilled feed, feathers, and fecal matter that are collected from living quarters where poultry is raised. This material is then used in cattle feed in some areas of the country where cattle and large poultry raising operations are located near each other. Poultry feed may legally contain protein that is prohibited in ruminant feed, such as bovine meat and bone meal. The concern is that spillage of poultry feed in the chicken house occurs and that poultry feed (which may contain protein prohibited in ruminant feed) is then collected as part of the "poultry litter" and added to ruminant feed;

- A ban the use of "plate waste" as a feed ingredient for ruminants. Plate waste consists of uneaten meat and other meat scraps that are currently collected from some large restaurant operations and rendered into meat and bone meal for animal feed. As was pointed out in the press conference, the use of "plate waste" confounds FDA's ability to analyze ruminant feeds for the presence of prohibited proteins, compromising the Agency's ability to fully enforce the animal feed rule;

- A requirement that equipment, facilities or production lines of animal feed mills be dedicated to non-ruminant animal feeds if they use protein that is prohibited in ruminant feed to prevent cross-contamination. Currently, some equipment, facilities and production lines process or handle prohibited and non-prohibited materials and make both ruminant and non-ruminant feed -- a practice which could lead to cross-contamination.[1]

There was never an interim final rule promulgated. It became apparent that ferocious industry opposition to these proposed measures scuttled FDA's attempts to close most of the loopholes in the current animal feed ban regulations. The agency, along with various agencies of the United States Department of Agriculture (USDA), issued an Advanced Notice for Proposed Rulemaking (ANPRM) in July 2004 (69 FR 42287) that further delayed action on protecting animal and human health, and instead, seemed to chart a new course for FDA with the major focus being on the removal of specified risk materials (SRMs) from all animal feed. The current proposed rule reflects that policy shift.

We believe that the proposed rule is inadequate for the following reasons:

First, FDA will have to rely on the current inspection practices of the Food Safety and Inspection Service (FSIS) at USDA to ensure that SRMs are properly removed. Recent reports indicate that those practices are deficient and inadequate to prevent contaminated materials from entering the animal and human food supplies:

- Current FSIS rules require removal of SRMs from cattle over 30 months of age. There have been instances of cattle under 30 months that have been infected with BSE, so we believe that the 30-month demarcation should be lowered;

- The dentition method used by FSIS to age cattle is not precise enough. Without an animal identification system in place, it is virtually impossible to be certain of the age of cattle being slaughtered;

[1] http://www.hhs.gov/news/press/2004pres/20040126.html

- Because FSIS is relying on the employees of slaughtering facilities to make the age determinations, there is no guarantee that SRMs are actually being removed from cattle over 30 months of age. In fact, a recent response to a Freedom of Information Act request made by the consumer organization Public Citizen indicates that there have been instances where the FSIS regulations on SRM removal have been violated.[2] Until the inspection regime is changed to give FSIS inspection personnel the authority and the responsibility to perform the aging function, there is a risk of contaminated material entering the animal and human food supplies. Since it takes only a small amount of contaminated material to infect a ruminant animal with BSE, we believe that FDA is leaving much to chance under the proposed rule.

Second, the FDA surveillance program for feed mills is still inadequate. While there have been improvements over the past several years, the frequency of inspection is still deficient, and there are still weaknesses in enforcement of reporting requirements. Recent Government Accountability Office reports on this issue support our contention.[3] In light of these criticisms, we are baffled why the FDA decided to drop its requirement of feed mills that process both ruminant and non-ruminant feed to segregate their operations to prevent cross-contamination. If FDA continues to suffer from a shortage of inspection personnel, then the industry should be required to institute the most stringent of practices to prevent contaminated material from entering the animal and human food supplies.

Third, FDA argues that the new rule would be viewed favorably by our trading partners that have suspended beef trade with the United States (70 FR 58587). While Japan, one of our largest trading partners, recently announced lifting the ban on the importation of U.S. beef, it is only accepting meat from cattle that are 21 months old or younger, and there is a requirement that SRMs be removed from these younger animals prior to export.[4] Furthermore, Japanese consumers are sill overwhelmingly leery of eating U.S. beef because they do not believe enough has been done by our government to prevent BSE.[5]

Another large trading partner, South Korea, still has not lifted its ban on U.S. beef. Among the concerns expressed by South Korean officials included the age determination of the cattle slaughtered for meat exported to that country.[6] Recent Korean press reports indicate that trade may not reopen until late 2006, at the earliest.

For all of the reasons cited above, we believe that FDA needs to provide further restrictions in the

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[2]http://www.citizen.org/pressroom/release.cfm?ID=2024

[3]http://www.gao.gov/new.items/d05101.pdf
http://www.gao.gov/new.items/d06157r.pdf

[4]http://mdn.mainichi-msn.co.jp/national/news/20051212p2a00m0na009000c.html

[5]http://www.cattlenetwork.com/content.asp?contentid=14555

[6]http://www.koreaherald.co.kr/SITE/data/html_dir/2005/12/20/200512200009.asp

animal feed rule. The agency should strive to eliminate one hundred percent of the remaining risk to animal and human health, and not cave in to industry pressure.

Should you have questions regarding our comments, please feel free to contact me at (202) 797-6550.

Sincerely,

Wenonah Hauter
Executive Director
Food and Water Watch